

AMENDMENTS TO THE CLAIMS

The following Listing of Claims will replace all prior versions and listings of the claims in this application:

Listing of Claims:

- 1-109. (canceled)
110. (new) A pharmaceutical composition comprising a hydrophilic or macromolecular drug and, as an enhancer for delivery of the drug to an intestine, a salt of a medium chain fatty acid or a medium chain fatty acid derivative having a carbon chain length of from 6 to 20 carbon atoms, wherein the enhancer and the composition are solids at room temperature.
111. (new) The composition of claim 110, wherein the carbon chain length is from 8 to 14 carbon atoms.
112. (new) The composition of claim 110 wherein the enhancer is a sodium salt of a medium chain fatty acid.
113. (new) The composition of claim 112, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.
114. (new) The composition of claim 110 wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.
115. (new) The composition of claim 114, wherein the polysaccharide is low molecular weight heparin.
116. (new) The composition of claim 115, wherein the peptide is luteinising hormone-releasing hormone analog.
117. (new) The composition of claim 110, wherein the drug is selected from the group consisting of unfractionated heparin, hirudin, insulin, calcitonin,

calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, interferons, somatropin, somatotropin, somatostatin, insulin-like growth factor, luteinising hormone-releasing hormone, tissue plasminogen activator, thyrotropin-releasing hormone, growth hormone-releasing hormone, antidiuretic hormone, leuprolide, euprolide acetate, goserelin, goserelin acetate, genotropin, nafarelin, buserelin, Factor VIII, interleukins, cyclosporin, vasopressin, desmopressin, parathyroid hormone, oxytocin, estradiol, growth hormones, and salts and derivatives thereof.

118. (new) The composition of claim 110, wherein the drug and the enhancer are present in a ratio of from 1:100,000 to 10:1 (drug:enhancer).
119. (new) The composition of claim 110, further comprising at least one auxiliary excipient.
120. (new) A solid oral dosage form comprising the composition of claim 110.
121. (new) The dosage form of claim 120, wherein the dosage form is a tablet, a capsule or a multiparticulate.
122. (new) The dosage form of claim 120, wherein the dosage form is a delayed release dosage form.
123. (new) The dosage form of claim 120, wherein the composition is in the form of a tablet.
124. (new) The dosage form of claim 123, wherein the tablet is a multilayer tablet.
125. (new) The dosage form of claim 120, wherein the dosage form further comprises a rate-controlling polymer material.
126. (new) The dosage form of claim 125, wherein the rate-controlling polymer material is HPMC.

127. (new) The dosage form of claim 125, wherein the rate-controlling polymer material is a polymer derived from acrylic or methacrylic acid and their respective esters or copolymers derived from acrylic or methacrylic acid and their respective esters.
128. (new) The dosage form of claim 125, wherein the composition is compressed into a tablet prior to coating with the rate-controlling polymer material.
129. (new) The dosage form of claim 128, wherein the tablet is a multilayer tablet.
130. (new) The dosage form of claim 120, wherein the composition is in the form of a multiparticulate.
131. (new) The dosage form of claim 130, wherein the multiparticulate comprises discrete particles, pellets, minitabets, or combinations thereof.
132. (new) The dosage form of claim 131, wherein the multiparticulate comprises a blend of two or more populations of particles, pellets, minitabets, or combinations thereof having different in vitro or in vivo release characteristics.
133. (new) The dosage form of claim 130, wherein the multiparticulate is encapsulated in a hard or soft gelatin capsule.
134. (new) The dosage form of claim 133, wherein the capsule is coated with a rate-controlling polymer material.
135. (new) The dosage form of claim 130, wherein the multiparticulate is incorporated into a sachet.
136. (new) The dosage form of claim 131, wherein the discrete particles, pellets, minitabets, or combinations thereof are compressed into a tablet.

137. (new) The dosage form of claim 136, wherein the tablet is coated with a rate-controlling polymer material.
138. (new) The dosage form of claim 136, wherein the tablet is a multilayer tablet.
139. (new) The dosage form of claim 137 wherein the tablet is a multilayer tablet.
140. (new) The solid oral dosage form of claim 120, wherein the composition is in the form of a delayed release enteric coated tablet.
141. (new) The solid oral dosage form of claim 140, wherein the enhancer is sodium caprate.
142. (new) A pharmaceutical composition comprising a hydrophilic or macromolecular drug and, as an enhancer for delivery of the drug to an intestine:
- (i) a salt of a medium chain fatty acid having a carbon chain length of from 6 to 20 carbon atoms;
 - (ii) a medium chain fatty acid halide derivative, a medium chain fatty acid anhydride derivative, or a medium chain fatty acid glyceride derivative, each of said derivatives having a carbon chain length of from 6 to 20 carbon atoms;
 - (iii) the fatty acid salt of clause (i) having at the end opposite the fatty acid salt an acid halide, acid anhydride, or glyceride moiety;
 - (iv) an acid halide derivative of clause (ii) above having at the end opposite of the halide portion an acid halide, acid anhydride, or glyceride moiety;
 - (v) an anhydride derivative of clause (ii) above having at the end opposite of the anhydride an acid anhydride, acid halide, or glyceride moiety; or

- (vi) a glyceride derivative of clause (ii) above having at the end opposite of the glyceride portion a glyceride, acid halide, or acid anhydride moiety;

wherein the composition and the enhancer are solids at room temperature.

143. (new) A solid oral dosage form comprising the composition of claim 142.
144. (new) A pharmaceutical composition comprising a hydrophilic or macromolecular drug and an enhancer for delivery of the drug to an intestine, wherein the only enhancer present in the composition is a salt of a medium chain fatty acid or a medium chain fatty acid derivative having a carbon chain length of from 6 to 20 carbon atoms.
145. (new) The composition of claim 144, wherein the enhancer is a salt of a fatty acid having a carbon chain length of from 8 to 14 carbon atoms.
146. (new) The composition of claim 144 wherein said fatty acid salt is a sodium salt.
147. (new) The composition of claim 146, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.
148. (new) The composition of claim 144 wherein the drug is a polysaccharide, an oligosaccharide, a protein or a peptide.
149. (new) The composition of claim 148, wherein the polysaccharide is low molecular weight heparin.
150. (new) The composition of claim 149, wherein the peptide is luteinising hormone-releasing hormone analog.
151. (new) The composition of claim 144, wherein the drug is selected from the group consisting of unfractionated heparin, hirudin, insulin, calcitonin,

calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, interferons, somatropin, somatotropin, somatostatin, insulin-like growth factor, luteinising hormone-releasing hormone, tissue plasminogen activator, thyrotropin-releasing hormone, growth hormone-releasing hormone, antidiuretic hormone, leuprolide, euprolide acetate, goserelin, goserelin acetate, genotropin, nafarelin, buserelin, Factor VIII, interleukins, cyclosporin, vasopressin, desmopressin, parathyroid hormone, oxytocin, estradiol, growth hormones, and salts and derivatives thereof.

152. (new) The composition of claim 144, wherein the drug and the enhancer are present in a weight ratio of from 1:100000 to 10:1 (drug:enhancer).
153. (new) A solid oral dosage form comprising the composition of claim 144.
154. (new) The dosage form of claim 153, wherein the composition is in the form of a tablet, a capsule or a multiparticulate.
155. (new) The dosage form of claim 153, wherein the dosage form is a delayed release dosage form.
156. (new) The dosage form of claim 153, wherein the composition is in the form of a tablet.
157. (new) The dosage form of claim 156, wherein the tablet is a multilayer tablet.
158. (new) The dosage form of claim 153, wherein the dosage form further comprises a rate-controlling polymer material.
159. (new) The dosage form of claim 158, wherein the rate-controlling polymer material is HPMC.
160. (new) The dosage form of claim 158, wherein the rate-controlling polymer material is a polymer derived from acrylic or methacrylic acid and their

respective esters or copolymers derived from acrylic or methacrylic acid and their respective esters.

- 161. (new) The dosage form of claim 158, wherein the composition is compressed into a tablet prior to coating with the rate-controlling polymer material.
- 162. (new) The dosage form of claim 161, wherein the tablet is a multilayer tablet.
- 163. (new) The dosage form of claim 153, wherein the composition is in the form of a multiparticulate.
- 164. (new) The dosage form of claim 163, wherein the multiparticulate comprises discrete particles, pellets, minitabets, or combinations thereof.
- 165. (new) The dosage form of claim 164, wherein the multiparticulate comprises a blend of two or more populations of particles, pellets, minitabets, or combinations thereof having different in vitro or in vivo release characteristics.
- 166. (new) The dosage form of claim 163, wherein the multiparticulate is encapsulated in a hard or soft gelatin capsule.
- 167. (new) The dosage form of claim 166, wherein the capsule is coated with a rate-controlling polymer material.
- 168. (new) The dosage form of claim 163, wherein the multiparticulate is incorporated into a sachet.
- 169. (new) The dosage form of claim 164, wherein the discrete particles, pellets, minitabets, or combinations thereof are compressed into a tablet.
- 170. (new) The dosage form of claim 169, wherein the tablet is coated with a rate-controlling polymer material.

171. (new) The dosage form of claim 169, wherein the tablet is a multilayer tablet.
172. (new) The dosage form of claim 170 wherein the tablet is a multilayer tablet.
173. (new) The composition of claim 144, wherein the enhancer is selected from the group consisting of:
- (a) an acid salt, acid halide, acid anhydride, or glyceride of a fatty acid having a carbon chain length of from 6 to 20 carbon atoms; and
 - (b) a derivative of clause (a) which is a difunctional in that it has on the end of the carbon chain opposite the acid salt group an acid halide, an acid anhydride, or a glyceride moiety.
174. (new) The composition of claim 144, wherein the composition and the enhancer are solids at room temperature.
175. (new) A process for the manufacture of a composition in solid oral dosage form comprising the steps of:
- a) providing a blend comprising a hydrophilic or macromolecular drug and, as an enhancer for delivery of the drug to an intestine:
 - (i) a salt of a medium chain fatty acid having a carbon chain length of from 6 to 20 carbon atoms;
 - (ii) a medium chain fatty acid halide derivative, a medium chain fatty acid anhydride derivative, or a medium chain fatty acid glyceride derivative, each of said derivatives having a carbon chain length of from 6 to 20 carbon atoms;
 - (iii) the fatty acid salt of clause (i) having at the end opposite the fatty acid salt an acid halide, an acid anhydride, or glyceride

moiety;

- (iv) an acid halide derivative of clause (ii) above having at the end opposite of the halide portion an acid halide, acid anhydride, or glyceride moiety;
- (v) an anhydride derivative of clause (ii) above having at the end opposite of the anhydride an acid anhydride, acid halide, or glyceride moiety; or
- (vi) a glyceride derivative of clause (ii) above having at the end opposite of the glyceride portion a glyceride, an acid halide, or acid anhydride moiety;

wherein the blend and the enhancer are solids at room temperature; and

- b) forming the solid oral dosage form from the blend by:
 - i) direct compression of the blend; or
 - ii) granulating the blend to form a granulate for incorporation into said solid oral dosage form.

176. (new) A method for the treatment of a medical condition comprising the step of administering orally to a patient suffering from said medical condition a therapeutically effective amount of the composition of claim 110.

177. (new) A method for the treatment of a medical condition comprising the step of administering orally to a patient suffering from said medical condition a therapeutically effective amount of the composition of claim 144.